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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,041	12/26/2001	Luc Desnoyers	P3030R1C8	4333

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EXAMINER

JIANG, DONG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,041

Applicant(s)

DESNOYERS ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26, 35, 36 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26, 35, 36 and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's amendment filed on 24 November 2003 is acknowledged and entered. Following the amendment, claims 26 and 35 are amended, and claims 27-29, 32-34 and 37 are canceled.

Currently, claims 22-26, 35, 36 and 38-41 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 27-29, 32-34 and 37 are moot as the applicant has canceled the claims.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 is incomplete for omitting essential elements. The claim is limited by a hybridization method under "stringent conditions". However, the claim recites neither hybridization conditions to ensure that any hybridized nucleic acid will comprise specific sequence within the meaning of the disclosure, nor process steps which would effect the removal of nonspecific hybridization complexes. The specification does not clearly define such conditions. Examples of "stringent conditions" are noted in the specification (page 80, the second paragraph). However, examples of such fall within the intended definition, and are not considered, in themselves, to provide definitive conditions for the hybridization. [As the target sequence is specific, an artisan needs to know the specific corresponding hybridization conditions in order to practice the claimed invention. Without a clear delineation of

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hybridization conditions, one can not determine the metes and bounds of nucleic acids within the limitations of the claim.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 36 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a nucleic acid of SEQ ID NO:1, and a nucleic acid encoding a polypeptide of SEQ ID NO:2, does not reasonably provide enablement for claims to hybridization variants thereof (claim 35, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for the reasons set forth in the previous Office Action, paper No. 8, mailed on 20 March 2003, at pages 4-6, and for the reasons below.

Applicants argument filed on 24 November 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 7 of the response, the applicant argues that claim 35 has been amended to recite hybridization under stringent conditions, and therefore, the claim is enabled because one of ordinary skill in the art can easily make and use the claimed hybridization variants without undue experimentation. This argument is not persuasive for the following reasons. Although the limitation of "under stringent conditions" is added to the claim, the invention is still not commensurate in scope with the claim because it is well known in the art that hybridization will occur even under stringent conditions if there is only local identity between two molecules whose sequences might be totally divergent outside of that region. Such hybridized molecules may encode proteins capable of inducing chondrocyte redifferentiation, yet having other distinct biological functions from those of the SEQ ID NO:2. The specification provides no guidance as to a specific hybridization condition for obtaining the claimed species, or working examples of

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any such variants which would be within the limitations of the claims. Therefore, it would require undue experimentation in order to make the claimed invention in its full scope.

Claims 35 and 36 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous Office Action, paper No. 8, mailed on 20 March 2003, at pages 6-8.

Applicants argument filed on 24 June 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 18 of the response, the applicant argues that amended claims 35-37 are described in sufficient detail to show possession of the claimed invention by inventors, and claim 35 has been amended to include the functional limitation. This argument is not persuasive because although the amended claim 35 recites the functional limitation, the specification provides no correlation between the sequence structure of SEQ ID NO:2 and the function, i.e., it does not detail any substructures from SEQ ID NO:2 that retain the function. As hybridization would happen between homologous polynucleotide sequences, which may not necessarily correlate to a functional activity of the polypeptide encoded thereby. The specification does not disclose any of such hybridization variants meeting the limitations of the claims, one of skill in the art would have no basis to derive the claimed ranges of hybridization variants from the instant disclosure, and thus, would not be able to envision the detailed chemical structure of the encompassed and to make such variants even though the level of skill and knowledge in the art is high.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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Claims 22-26, 35, 36 and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Piddington et al., US 6,521,233 B1, for the reasons of record set forth in the last Office Action, paper No. 10, mailed on 21 August 2003, at page 4.

Applicants argument filed on 24 November 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 8 of the response, the applicant argues that Piddington does not anticipate the present claims because Piddington fails to enable one of skill in the art to make and use the claimed invention, and that a claim can only be anticipated by a reference if the publication describes the claimed invention with sufficient enabling detail to place the public in possession of the invention, according to the case laws cited by applicants. This argument is not persuasive because Piddington teaches a nucleic acid having SEQ ID NO:1, which encodes a human polypeptide, zacrp3, having an amino acid sequence 100% identical to SEQ ID NO:2 of the instant invention. As such, Piddington's description of the nucleic acid sequence and the amino acid sequence encoded thereby clearly provides sufficient enabling detail to place the public in possession of the invention, as any one of skill in the art would be able to make the nucleic acid and polypeptide based on the sequences taught by Piddington. Further, in *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, 346 F.3d 1051 (Fed. Cir. 2003), cited by applicants, it is said that "enablement requires that 'the prior art reference must teach one of ordinary skill in the art to make *or* carry out the claimed invention without undue experimentation'". The Piddington reference meets such an enablement requirement as it teaches how to make the polypeptide. With respect to the requirement that the anticipating reference must enable to make *and use* the claimed invention, the Examiner is not able to locate such recitation in the case law cited by applicants. Further, the statute of 102(e) itself merely requires that "the invention was *described* in ...". The present invention is directed to a product, an isolated polypeptide, which sequence was disclosed in the prior art reference. As such, the polypeptide of the present invention has been well described by the prior art reference, and the prior art reference meets the anticipating requirement of 102(e).

At page 9 of the response, the applicant further argues that the Piddington provisional application (filed on April 20, 1999, earlier than the effective filing date of the present application) fails to teach how to make and use invention of the present claims without undue

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experimentation as the present claims recite isolated nucleic acid variants that encode polypeptides having ability to induce chondrocyte redifferentiation, and the Piddington provisional application does not recognize such ability of the polypeptides. This argument is not persuasive because the Piddington provisional application teaches the nucleic acid sequence and the amino acid sequence encoded thereby, wherein the nucleic acid sequence meets the limitation of “at least 80% (or 85, 90, 95, 99%)” in the present claims. The present claims, as written, encompass the prior art sequence, i.e., the nucleic acid encoding a polypeptide 100% identical to SEQ ID NO:2. Further, the disclosed nucleic acid and amino acid sequences enables one of skill in the art to make the claimed invention. With respect to the functional limitation, the ability to induce chondrocyte redifferentiation is inherent because the presently claimed polypeptide SEQ ID NO:2 is 100% identical to that of the prior art. According to MPEP, “when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent”, and “if the composition is physically the same, it must have the same properties” (see MPEP 2112.01). The present invention is directed to a product, an isolated nucleic acid encoding a polypeptide having the same amino acid sequence as that of the prior art. Although Piddington did not recognize the presently recited property, the newly discovered property of a known product is inherent. As such, the newly discovered property of the polypeptide to induce chondrocyte redifferentiation does not render the instant claims novel, and they are not patentable over the prior art.

Conclusion:

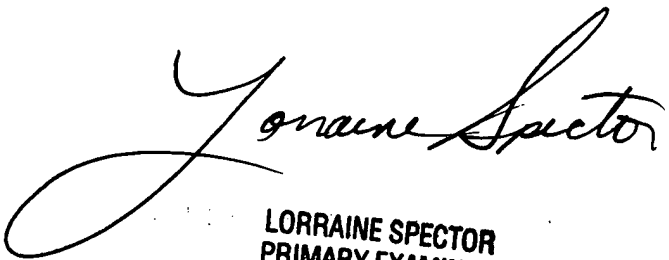
No claim is allowed.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
2/16/04